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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,935	05/03/2001	David F. Woodward	D2914	6555

33197 7590 12/31/2002

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,935	WOODWARD ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41 and 43-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41 and 43-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of supplemental prior art and amendment B filed 09/16/02 and request for continued examination under 37 CFR 1.114 and preliminary amendment filed 10/15/02.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/02 has been entered.

Claims 36-41 and 43-69 are pending.

2. References are cited in the specification. If applicants wish the background references cited in the specification to be considered, it is respectfully suggested to applicants that the references be submitted under 37 CFR 1.98 (b) including a completed form 1449. See MPEP § 609 A(1).

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The alteration to the residence address for inventor Woodward is neither dated no initialed.

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). The declaration fails to identify the application by the serial number.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40 and 63 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for quinoxaline, does not reasonably provide enablement for all quinoxaline derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following Wands factors are considered:

1. <u>The quantity of experimentation necessary</u>

Applicants have not stated in the specification what the quinoxaline derivatives are. On page 3 of the specification, starting at line 3 from the bottom, stating that examples of quinoxaline derivatives include ... does not specifically indicate which of the derivatives are applicable in the invention. Two derivatives and their salts are listed and the list is not exhaustive and the claims may have recited those quinoxalines. Secondly, page 11, paragraph 1, halides of 2-imidozolin-2-ylamino) quinoxaline are listed as examples of the

quinoxaline derivatives and in paragraph 2 it is stated that "useful quinoxaline derivatives are well known" without an indication of what quinoxaline derivatives are applicable in the application. Since the specification failed to state which quinoxaline derivatives would be applicable, the amount or quantity of experimentation would be unreasonable and of undue burden to one of ordinary skill or one of skill in the art to through experimenting the invention with all the known and yet to be discovered quinoxaline derivatives to arrive at those derivatives that would work in the invention.

2. The amount of direction or guidance presented

Applicants presented no guidance or direction as to what quinoxaline derivatives are workable in the application because there is no direction that states that quinoxalines derivatives are ....

3. The predictability or unpredictability

Exemplification was given only for Brimonidine quinoxaline and it will require a great deal of experimentation to determine which of the quinoxaline derivatives would work in the invention.

4. The breadth of the claims

The scope of the claims is not commensurate with the disclosure because the specification does not provide enablement for all quinoxaline derivatives. The person of ordinary skill would be required to perform undue experimentation to determine all the quinoxaline derivatives that may work in the invention.

Applicants may overcome this rejection by either reciting the quinoxaline derivatives that are enabled for in the specification (see pages 3, 4 and 11 of the specification) or to amend the specification to say that quinoxaline derivatives are ....

7. Claims 40 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of derivatives after quinoxaline renders the claims indefinite because is not clear which of the quinoxaline derivatives are workable in the invention. Applicants may overcome this rejection by amending the claim to remove the term that renders the claims indefinite.

8. Claims 41 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 64 recite "NMDA antagonist" without an initial definition/description of what "NMDA" stands for. An abbreviation may not be used in a claim without an initial definition of what that abbreviation is. Applicants may overcome this rejection by initially reciting a definition for the term and enclosing the abbreviation in parenthesis for subsequent use.

Applicants state in the remarks that derivatives are any substituted or modified material that has the characteristic chemical structure. However, as discussed above, reciting "quinoxaline derivatives" in the absence of specific teaching of what those derivatives are places undue burden on any one to determine what those derivatives are and to experiment with all

known and yet to be discovered quinoxaline derivatives in order to determine which of the quinoxaline derivatives would work in the invention. Listing examples of quinoxaline derivatives does not direct one to know the derivatives, in this case quinoxaline derivatives that would work in the invention.

The word derivatives may be deleted from the claims of interest, or the specific derivatives enabled for by the specification may be claimed or those derivatives that satisfy the invention may be recited using a Markush language.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 36-41, 43, 44, 47-50, 53, 54, 57 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanssler et al. (Derwent Database on West, DE 3309765 A).

Hanssler teaches a composition comprising a quinoxaline and a vegetable oil or linoleic acid or lecithin (abstract). The invention broadly claims a composition comprising a therapeutic component and an efficiency-enhancing component selected from the group consisting of anionic polymer and fatty acids. It is inherent that a complex forms in a mixture of therapeutic

component and fatty acid. Quinoxaline is a therapeutic component and linoleic acid is a fatty acid. Future intended use is not critical in a composition claim. Thus the teaching of Hanssler meets the limitations of the claims.

11. Claims 36, 37, 41, 43, 44, 46-50, 53, 54, 57 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2272684 (Derwent Database on West).

FR 2272684 discloses a composition comprising fatty acid and antibiotic (abstract). A complex would inherently form a complex in a mixture comprising a therapeutic component and fatty acid. And the invention broadly claims a composition comprising a therapeutic component and an efficiency-enhancing component selected from the group consisting of anionic polymer and fatty acids. Specifically FR 2272684 lists oleic acid, arachidonic acid, linolenic acid and linoleinic as the fatty acids. Future intended use is not critical in a composition claim. Thus the teachings of FR 2272684 meet the limitations of the claims.

12. Claims 36, 37, 43-45, 47-50, 53, 54 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelley et al. (US 5,118,493).

Kelly teaches a composition comprising a therapeutically effective amount of cyclosporin in combination with omega-3-fatty acids (claim 1). The omega-3-fatty acid is eicosapentaenoic acid (claims 2 and 8), docosahexanoic acid (claims 3 and 9) and fish oil (claims 6 and 10). Future intended use is not critical in a composition claim. The application broadly claims a composition comprising a therapeutic component and fatty acids and the claims are thus anticipated by Kelly.

13. Claims 36-41, 47-50, 53-55, 57, 58, 60-66, 68 and 69 rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al. (US 6,242,442)

Dean discloses a composition comprising brinzolamide, brimonidine tartrate, mannitol, purified water, tyloxapol, carbopol, benzalkonium chloride, sodium chloride and disodium EDTA (examples 6-9). Brinzolamide is a carbonic anhydrase inhibitor (column 1, lines 11-13 and column 3, line 31) and brimonidine tartrate is quinoxaline and alpha-2-adrenergic agonist (column 1, lines 19-26). Water is a carrier and benzalkonium chloride is an antiseptic. Dean teaches that the pH of the brinzolamide and brimonidine formulation is between 6.5 to 7.8 (column 5, lines 28-32). The teachings of Dean meet the limitations of the claims.

Response to Remarks

Regarding the rejections under 35 U.S.C. 102, applicants state that examiner failed to provide evidence to support that the compositions of the cited references would inherently form complexes and that without evidence to the contrary, applicants maintain that the cited references do not anticipate the claims.

14. Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive. The cited references teach applicants' broad compositions. Nothing in applicants' composition indicates that a complex would not form in the composition of the cited references. The circumstance in the Monsanto case cited by applicants is clearly different from that in the present situation. In the Monsanto decision, the features were hollow ribs versus non-hollow ribs. In the present case, it is a broad composition where therapeutic agent forms a complex with efficacy enhancing component. No amounts and/or conditions were recited that would allow the composition of the application to form a complex and exclude the same composition in the prior art from forming a complex. In this case the prior art teaches a composition comprising a therapeutic component and efficacy enhancing component; and the examined claims are directed

to a composition comprising a therapeutic component and efficacy enhancing component. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See in re Spada, 911 F.2d 705, 709, 15 USPQD2d 1655, 1658 (Fed. Cir. 1990); In re Best, 562 F.2d at 1255, 195 USPQD at 433; Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 36-41 and 43-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 09/848.249. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims a composition comprising a therapeutic agent and efficacy enhancing components in the generic claim. The therapeutic agent claimed is alpha-2-adrenergic agonist (claim 4) and the efficacy-enhancing component is selected from the group consisting of anionic polymers and fatty acids (generic claim 1). The co-pending application number 09/848249 claims a composition comprising alpha-2-adrenergic

agonist and fatty acids in the generic claim and thus the claims of the co-pending application are encompassed in the examined application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner thanks applicants for their willingness to submit terminal disclaimer when allowable subject matter is indicated. However, the rejection is made and will be withdrawn upon receipt of a terminal disclaimer.

17. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is respectfully requested in correcting any errors of which applicants may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
December 30, 2002